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PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
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Erika Jensen-Jarolim *et al.*	)	Group Art Unit: 1648
	)	
Application No.: 10/501,402	)	Examiner: Le, E.M.
	)	
Filed: January 15, 2003	)	
	)	
For: *Oral Vaccination*	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION TO THE DIRECTOR UNDER 37 C.F.R. §§ 1.144 AND 1.181 TO WITHDRAW FINAL RESTRICTION REQUIREMENT

Sir:

Applicants submit herewith a petition to the director to withdraw a final species election requirement. This petition is proper under 37 C.F.R. §§ 1.144 and 1.181. In accordance with 37 C.F.R. § 1.181(b), this petition provides the following:

I. Statement of the Facts Involved;

II. Points to be Reviewed; and

III. Action Requested.

The final species election requirement is based on the allegation that the claims are directed to more than one species that lack unity of invention because they are not linked as to form a single general inventive concept under PCT Rule 13.1. Applicants respectfully assert that this species requirement is improper and request that it be withdrawn and that the elected group of claims be examined free of any required species election requirement.

I. Statement of Facts Involved

a. Restriction and Species Requirements

In response to the Examiner's Restriction Requirement dated May 17, 2007, Applicant elected Group I (claims 11-33) for examination, with traverse.[1] The Examiner also made an Election of Species Requirement regarding the following species: Antacids, H_2-receptors, and Proton Pump Inhibitors. *See* May 17, 2007 Office Action at 3. Applicant provisionally elected, with traverse, the Antacid species. *See* Reply to Restriction Requirement, filed June 18, 2007. Applicant notes that reasons for the traverse were provided in the above-mentioned reply and are reiterated below. Following Applicants' last reply, the restriction was made final. *See* December 21, 2007 Office Action at page 3.

b. Pending and Withdrawn claims

Claims 11-12, 16-67 are pending.[2] As a result of restriction and elections, claims 17-20 and 32-66 have been withdrawn. *See* December 21, 2007 Office Action Summary. Applicants note that withdrawn claims 17 to 20 have been amended in view of claims 13-16 being cancelled. A current listing of the claims, including amendments that are concurrently being made, is provided below.

LISTING OF CLAIMS

Claims 1-10 (Cancelled).

Claim 11 (Currently Amended). A vaccine comprising an antigenically active substance and a gastric acid reducing substance**, wherein the gastric acid reducing substance is selected from the group consisting of antacids which act protectively through the mucous membrane, H_2-receptor agonists and proton pump inhibitors**.

Claim 12 (Previously Presented). The vaccine of claim 11, wherein the gastric acid reducing substance is present in an amount sufficient to increase the pH in the stomach to between pH 4 and pH 7.

Claim 13 (Cancelled).

Claim 14 (Cancelled).

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[1] The Examiner's Restriction Requirement with regards to Groups I and II is not appealed.
[2] Applicants note that they are concurrently filing a response to the December 21, 2007 Office Action. The response makes certain claim amendments, cancels certain claims, and adds an additional claim.

Claim 15 (Cancelled).

Claim 16 (Cancelled).

Claim 17 (Currently Amended). The vaccine of claim ~~15~~11, wherein the proton pump inhibitors are selected from the group consisting of omeprazole, lansoprazole, pantoprazole and rabeprazole.

Claim 18 (Currently Amended). The vaccine of claim ~~16~~12, wherein the proton pump inhibitors are selected from the group consisting of omeprazole, lansoprazole, pantoprazole and rabeprazole.

Claim 19 (Currently Amended). The vaccine of claim ~~15~~11, wherein the H_2 receptor antagonists are selected from the group consisting of cimetidine, ranitidine, omexetidine, famotidine, roxatidine and nizatidine.

Claim 20 (Currently Amended). The vaccine of claim ~~16~~12, wherein the H_2 receptor antagonists are selected from the group consisting of cimetidine, ranitidine, omexetidine, famotidine, roxatidine and nizatidine.

Claim 21 (Previously Presented). The vaccine of claim 11, wherein the antigenically active substance is one or more natural antigens, synthetic antigens, antigen mimotopes, or a combination thereof.

Claim 22 (Previously Presented). The vaccine of claim 12, wherein the antigenically active substance is one or more natural antigens, synthetic antigens, antigen mimotopes, or a combination thereof.

Claim 23 (Previously Presented). The vaccine of claim 21, wherein the natural antigen or synthetic antigen and/or antigen mimotopes are coupled to a carrier.

Claim 24 (Previously Presented). The vaccine of claim 22, wherein the natural antigen or synthetic antigen and/or antigen mimotopes are conjugated to a carrier.

Claim 25 (Previously Presented). The vaccine of claim 23, wherein the natural antigen or synthetic antigen and/or antigen mimotopes are conjugated to a carrier.

Claim 26 (Previously Presented). The vaccine of claim 22, wherein the antigen mimotopes are conjugated to a carrier as a monomer, dimer, trimer, or oligomer.

Claim 27 (Previously Presented). The vaccine of claim 23, wherein the antigen mimotopes are conjugated to a carrier as a monomer, dimer, trimer, or oligomer.

Claim 28 (Previously Presented). The vaccine of claim 26, wherein single or multiple monomeric, dimeric, trimeric, or oligomeric antigen mimotopes are bound to the carrier.

Claim 29 (Previously Presented). The vaccine of claim 27, wherein single or multiple monomeric, dimeric, trimeric, or oligomeric antigen mimotopes are bound to the carrier.

Claim 30 (Previously Presented). The vaccine of claim 11, wherein the antigenically active substance is a tumor antigen.

Claim 31 (Previously Presented). The vaccine of claim 12, wherein the antigenically active substance is a tumor antigen.

Claim 32 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof an effective amount of an antigenically active substance and an effective amount of a gastric acid reducing substance, wherein said method produces an immune response to the antigenically active substance.

Claim 33 (Withdrawn). A method of claim 32, wherein the gastric acid reducing substance is administered in an amount sufficient to increase the pH in the stomach to between pH 4 and pH 7.

Claim 34 (Withdrawn). The method of claim 32, wherein the antigenically active substance and gastric acid reducing substance are administered simultaneously.

Claim 35 (Withdrawn). The method of claim 32, wherein the antigenically active substance is administered after administration of the gastric acid reducing substance.

Claim 36 (Withdrawn). The method of claim 32, wherein the antigenically active substance and gastric acid reducing substance are released simultaneously in the stomach.

Claim 37 (Withdrawn). The method of claim 32, wherein the antigenically active substance is released in the stomach after release of the gastric acid reducing substance.

Claim 38 (Withdrawn). The method of claim 32, wherein the antigenically active substance is one or more natural antigens, synthetic antigens, antigen mimotopes, or a combination thereof.

Claim 39 (Withdrawn). The method of claim 38, wherein the natural antigen or synthetic antigen and/or antigen mimotopes are coupled to a carrier.

Claim 40 (Withdrawn). The method of claim 39, wherein the antigen mimotopes are conjugated to a carrier as a monomer, dimer, trimer, or oligomer.

Claim 41 (Withdrawn). The method of claim 32, wherein the antigenically active substance is a tumor antigen.

Claim 42 (Withdrawn). The method of claim 32, wherein the gastric acid reducing substance inhibits gastric acid formation or binds gastric acid.

Claim 43 (Withdrawn). The method of claim 32, wherein the gastric acid reducing substance is selected from the group consisting of antacids, H_2-receptor antagonists and proton pump inhibitors.

Claim 44 (Withdrawn). The method of claim 32, wherein the proton pump inhibitors are selected from the group consisting of omeprazole, lansoprazole, pantoprazole and rabeprazole.

Claim 45 (Withdrawn). The method of claim 15, wherein the H_2 receptor antagonists are selected from the group consisting of cimetidine, ranitidine, omexetidine, famotidine, roxatidine and nizatidine.

Claim 46 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 11, wherein said method produces an immune response to the antigenically active substance.

Claim 47 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 12, wherein said method produces an immune response to the antigenically active substance.

Claim 48 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 13, wherein said method produces an immune response to the antigenically active substance.

Claim 49 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 14, wherein said method produces an immune response to the antigenically active substance.

Claim 50 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 15, wherein said method produces an immune response to the antigenically active substance.

Claim 51 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 16, wherein said method produces an immune response to the antigenically active substance.

Claim 52 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 17, wherein said method produces an immune response to the antigenically active substance.

Claim 53 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 18, wherein said method produces an immune response to the antigenically active substance.

Claim 54 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 19, wherein said method produces an immune response to the antigenically active substance.

Claim 55 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 20, wherein said method produces an immune response to the antigenically active substance.

Claim 56 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 21, wherein said method produces an immune response to the antigenically active substance.

Claim 57 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 22, wherein said method produces an immune response to the antigenically active substance.

Claim 58 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 23, wherein said method produces an immune response to the antigenically active substance.

Claim 59 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 24, wherein said method produces an immune response to the antigenically active substance.

Claim 60 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 25, wherein said method produces an immune response to the antigenically active substance.

Claim 61 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 26, wherein said method produces an immune response to the antigenically active substance.

Claim 62 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 27, wherein said method produces an immune response to the antigenically active substance.

Claim 63 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 28, wherein said method produces an immune response to the antigenically active substance.

Claim 64 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 29, wherein said method produces an immune response to the antigenically active substance.

Claim 65 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 30, wherein said method produces an immune response to the antigenically active substance.

Claim 66 (Withdrawn). A method of vaccination comprising orally administering to a subject in need thereof the vaccine of claim 31, wherein said method produces an immune response to the antigenically active substance.

Claim 67 (New). A vaccine comprising an antigenically active substance and a gastric acid reducing substance, wherein the gastric acid reducing substance is sucralfate or carbenoxolone.

c. Final Species Requirement

The final species requirement is based on the following species:

Antacids: Original claims 1-16, 21-43, and 46-66.

H2-Receptor: Original claims 1-16, 19-43, and 45-66.

Proton Pump Inhibitors: Original claims 1-18, 21-44, and 46-66.

II. Points to be Reviewed

a. Examination of all the Species is not Burdensome

The requirement of unity of invention under PCT Rule 13.1 is met when there is a technical relationship among the inventions involving one or more "special technical features." PCT Rule 13.2. PCT Rule 13.2 is met for a claim that defines alternative compounds when:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present . . .; or

(B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

MPEP § 1850(III)(B) (emphasis added). However, the Examiner stated in the May 17, 2007 Office Action that "Unity of invention can be demonstrated by significant structural similarities. . . . [N]o significant structural similarities can be ascertained for the listed species." Office Action at 4. Applicants respectfully submited that the proper criteria for requiring an election of species have not been considered or met. See Response filed June 18, 2007.

Specifically, the Applicants argued that the Examiner failed to consider that the listed species belong to "a recognized class of chemical compounds in the art to which the invention pertains." "A recognized class of chemical compounds" means that "there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention." MPEP § 1850(III)(B). The listed species are all recognized as members of a class of chemical compounds that reduce the amount of gastric acid in the gastric region.

The claimed invention involves a vaccination wherein an antigenically active substance is introduced to the gastric region where conditions permit the formation of antibodies due to the gastric acid reducing substance. In the context of the claimed invention, antacids, H_2-receptor agonists, and proton pump inhibitors, have the common property or activity of reducing gastric acid. The Examiner rejected Applicants' argument and stated "the time of the invention was filed, antacids are well known in the art." December 21, 2007 Office Action at 2.

What the Examiner fails to further note, however, is that the inventive concept of the application is the **combination** of the antigenically active substance and the specific gastric acid reducing substance which results in an increased immune response as illustrated in Figure 1 of the instant application. Applicants also respectfully point out that the corresponding PCT International application was considered to have unity of invention during the international phase. Moreover, the antacid recited in amended claim 11 is not recognized in the prior art cited by the Examiner. Accordingly, Applicants respectfully request reconsideration and withdrawal of the outstanding election of species requirement.

III. Action Requested

Applicant respectfully requests that the final species election requirement be withdrawn and that the elected group of claims be examined free of any required species election requirement.

IV. Conclusion

Applicant respectfully requests reconsideration and withdrawal of the final election of species requirement.

> **EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 13-3250, reference No. 37488.00400. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

If the Directed finds that a telephone conference would further prosecution of this application, she is invited to contact the undersigned at 202-835-7553.

Respectfully submitted,

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March 21, 2008

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